

**REMARKS**

Claims 1-7 have been amended to more definitely set forth the invention and obviate the rejections. In addition, new claims 8-22 have been presented. Support for the subject matter of new claims 8-22 can be found in the Specification on the paragraph bridging pages 3 and 4, page 4, paragraph 3, page 5, paragraphs 2-4, and page 6, paragraph 3. The present amendment is deemed not to introduce new matter. Claims 1-22 are now in the application.

Reconsideration is respectfully requested of the rejection of Claims 1-7 under 35 U.S.C. 103(a) as being unpatentable over Lentini, et al. (WO 11/33803) and Katsuhiro (JP 01-165517) in view of Tanaka (USP 5,540,921).

The primary Lentini, et al. reference teaches a sunscreen composition comprising a fluoro-resin having a submicron in combination with a sunscreen agent and an oil component. Specifically, Lentini, et al. teaches a less irritating sunscreen product, achieved by reducing the amount of sunscreen agent such as octylmethoxy cinnamate, and other sunscreen agents such as TiO<sub>2</sub> (see USP '156, column 5, lines 1-4). Unlike the present invention, reduction in skin irritation is achieved by using a *fluorinated polymer powder (e.g., fluoro-resins powder, such as TEFLON powder)*. Lentini, et al. teaches that such fluorinated polymer powders boost the SPF (sun protection factor) of the sunscreen agent, which is achieved by strengthening the sunscreen effect of sunscreen agents such as octylmethoxy cinnamate. Because sunscreen agents (such as Octylmethoxy cinnamate) strengthen the sunscreensing ability via the fluorinated polymer powder, the content of the sunscreen agent such as octylmethoxy cinnamate caused of irritation

can be lowered, and the formulation can have a low irritation characteristic.

However, as previously argued herein, and as the Examiner has recognized on page 4 of the instant Office Action, Lentini, et al. fail to teach or suggest the hydrophobically treated zinc oxide powder, as claimed herein. Moreover, as the Examiner has also recognized in the instant Office Action, Lentini, et al. fails to disclose the glucoside claimed herein. Both of these components constitute important aspects or elements of the present invention, and are not taught or suggested by Lentini, et al.

As mentioned above, in contrast to the cited Lentini, et al. reference, the present invention does not intend to use fluororesin powders, such as TEFLON powder, for the purpose of reducing irritation, and octylmethoxy cinnamate and ZnO can be included in the composition without reducing the amount of same to avoid skin irritation. This important feature of the present invention is not taught or suggested by Lentini, et al.

The present inventors have found that a given amount (even a small amount of) octylmethoxy cinnamate, which does not cause irritation when applied alone, causes irritation to the skin if it is mixed with the powders of zinc oxide or titanium oxide. (see Specification, page 2, line 15 to 22). As it is known that octylmethoxy cinnamate causes irritation, the amount of irritation caused by octylmethoxy cinnamate is increased by mixing of same with powdered zinc oxide or titanium oxide in the formulation. In order to overcome the deficiency of the formulation having irritation, characteristically caused by octylmethoxy cinnamate and zinc oxide, the present inventors have unexpectedly discovered the new effect of POE or POP methyl glucoside, which is characterized by reducing the irritation.

In order to cure the deficiencies of Lentini, et al., the Examiner has cited the Katsuhiko, et al. reference. Katsuhiko, et al. disclose a cosmetic agent comprised of  $\text{TiO}_2$  and POE methyl glucoside, for use as a sunscreen formulation. However, Katsuhiko, et al. fail to address the issue of irritation caused by application to the skin of octylmethoxy cinnamate with  $\text{ZnO}$ , and the use of POE methyl glucoside as a component in an external skin preparation containing same, which acts as an agent capable of reducing the irritation caused by octylmethoxy cinnamate with  $\text{ZnO}$ . Further, unlike the present invention, Katsuhiko, et al. fail to teach or suggest that by adding POE methyl glucoside to a external skin preparation comprising octylmethoxy cinnamate and hydrophobically treated  $\text{ZnO}$ , the amount of the sunscreen agents can be maintained without an increase (and even with a decrease) in skin irritation. Rather, these teachings come only from the present invention, and constitute an important element or aspect thereof.

The secondary reference of Tanaka discloses a solid oil-in-water cosmetic composition. As the Examiner has stated, Tanaka does teach a zinc oxide powder, and the possible hydrophobic treatment thereof. However, like both Lentini, et al. and Katsuhiko, et al. discussed above, it is believed that Tanaka likewise fails to address the issue of skin irritation caused by application to the skin of octylmethoxy cinnamate with  $\text{ZnO}$ , and overcoming same by adding POE methyl glucoside to an external skin preparation comprising octylmethoxy cinnamate and hydrophobically treated  $\text{ZnO}$ . Rather, that teaching comes only from the instant application, and constitutes an important element or aspect of the present invention.

Office personnel should consider all rebuttal evidence that is timely presented by the applicants when reevaluating any obviousness determination. Rebuttal evidence may include evidence of “secondary considerations” such as commercial success, long felt but unsolved needs [and] failure of others, and may also include evidence of unexpected results. Federal Register Notice, volume 72, October 10, 2007, at 57534.

Although the Supreme Court recently rejected the requirement that there must be some teaching, suggestion or motivation in the prior art that would have led one of ordinary skill in the art to modify the prior art references to arrive at the claimed invention, the Court nonetheless indicated that the lack of any teaching, suggestion or motivation in the prior art may still be considered as one factor in the overall determination of obviousness. *KSR International Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_\_\_, 82 USPQ 2d 1385 (2007)

With respect to the second issue above, objective evidence of secondary considerations, such as unexpected results, are relevant to the issue of obviousness and must be considered in every case in which they are present. See MPEP 2141 II. It is the duty of the Examiner to evaluate such evidence. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed.Cir., 1983); and *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed.Cir., 1986), cert. denied, 480 U.S. 947 (1987).

Proof of an unexpected improvement can rebut a prima facie case of obviousness. *In re Murch*, 464 F.2d 1051, 175 USPQ 89 (CCPA, 1972). No matter how strong the prima facie case of obviousness made out by the PTO, it must be weighed against any factors to the contrary

brought out by the applicant in determining the validity of the conclusion of patentability unobviousness. *In re Lewis*, 443 F.2d 489, 170 USPQ 84 (CCPA, 1971). Therefore, facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion was reached, not against the conclusion itself. *In re Lilly & Co.*, 902 F. 2d 943, 14 USPQ 2d, 1741 (CAFC, 1990).

Conventionally, the amount of sunscreen agents such as octylmethoxy cinnamate and zinc oxide must be reduced so as to reduce skin irritation. However, in contrast to the Lentini, et al., Katsuhiro, et al. and Tanaka references cited herein, it is respectfully submitted that the present inventors unexpectedly discovered that skin irritation caused by application to the skin of a sunscreen composition comprised of octylmethoxy cinnamate with ZnO (zinc oxide) can be overcome by adding POE methyl glucoside to the sunscreen composition, *without* a concurrent reduction in the amount of the sunscreensing agents. In particular, tests were performed to determine the effectiveness of the claimed glucoside and, as described in the “continuous skin irritation test” section on pages 7-11 of the instant Specification, it was unexpectedly discovered that by adding the glucoside (namely POE methyl glucoside) claimed herein to a sunscreen composition comprising octylmethoxy cinnamate and ZnO, the skin irritation caused by the combination of these components can be reduced or eliminated.

In addition to the showings of unexpected results, as presented in the instant Specification and discussed above, evidence of secondary consideration in the form of *commercial success* is hereby presented in the form of an attached Declaration of Commercial Success Pursuant to MPEP 716.01(a), concerning the extremely successful sunscreen cosmetic composition having

the brand name "Anessa". As discussed therein, the "Anessa" brand sunscreen cosmetic composition, having the composition claimed herein, is being sold in Japan and other foreign countries.

Total sales of "Anessa" in Japan in 2003 were approximately 3.4 billion yen, in 2004 were approximately 5.1 billion yen, in 2005 were approximately 5.5 billion yen, and in 2006 were approximately 6.3 billion yen. In total, from 2003-2006, Shiseido Co., Ltd., the assignee herein, has sold approximately 20.3 billion yen worth of the "Anessa" product. It is believed that the commercial success of the "Anessa" product is attributable to the low skin irritation provided by the claimed combination of components herein.

It is strenuously urged that the evidence of unexpected results, as well as commercial success of the claimed composition hereby presented, rebuts any prima facie case of obviousness in the instant rejection. Consequently, the Examiner would be justified in no longer maintaining this rejection. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Atty Docket No. SHD-002-USA-P

Respectfully submitted

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**CERTIFICATE OF TRANSMISSION**

I hereby certify that this electronic transmission, consisting of a 14-page Amendment and 5-page Declaration of Commercial Success, in U.S. patent application serial No. 10/671,519, filed on September 29, 2003, is being electronically transmitted via EFS to the U.S. Patent and Trademark Office on September 17, 2008.

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